



# ATTENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-338WO		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/IB2004/000536		International filing date (day/month/year) 01.03.2004		Priority date (day/month/year) 28.02.2003
International Patent Classification (IPC) or national classification and IPC A61K9/20, A61K9/30, A61K31/4439				
Applicant RANBAXY LABORATORIES LIMITED et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 3 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  23.12.2004		Date of completion of this report  08.04.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Hedegaard, A  Telephone No. +49 89 2399-8644 		

INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITYInternational application No.  
PCT/IB2004/000536

DT09 Rec'd PCT/PTO 26 AUG 2005

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

## Description, Pages

1-12 as originally filed

## Claims, Numbers

1-39 received on 03.01.2005 with letter of 23.12.2004

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):
  4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-3, 5-7,10,13-14.17-18,21,23-26,29,31-33,36-37,39
	No: Claims	
Inventive step (IS)	Yes: Claims	1-3, 5-7,10,13-14.17-18,21,23-26,29,31-33,36-37,39
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-3, 5-7,10,13-14.17-18,21,23-26,29,31-33,36-37,39
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Re Item V.**

- 1 The following documents are referred to in this communication:

D1 : EP 1 004 305 A

D2 : WO 98/52564 A

Document D1 (see Table III) discloses stable preparations comprising a core including sodium rabeprazole (50 mg) and HPC (450 mg).

Document D2 (see example 3) discloses cores including and active drug and small amounts of low viscosity HPC (HPC-L Klucel). On p. 4, I. 4 pariprazole (= rabeprazole) is disclosed as an example of an active drug.

- 2 The subject-matter of claims 1-3, 5-7, 10, 13-14, 17-18 and 21 (composition); 23-26, 29, 31-33 and 36 (process); and 37 and 39 (method) is novel (Art. 33(2) PCT) since a core comprising rabeprazole and at least 10% w/w of low viscosity HPC has not been disclosed in any of the available prior art documents.

- 3 The subject-matter of claim 1 differs from D1 (see above under item 1) in that it selects a particular HPC, namely low viscosity HPC.

There is no hint in D1 (alone or in combination with any other document) that more stable compositions of rabeprazole can be obtained when including at least 10% w/w of low viscosity HPC in the core. Therefore, the subject-matter of claims 1-3, 5-7, 10, 13-14, 17-18, 21, 23-26, 29, 31-33, 36-37 and 39 is considered to involve an inventive step (Art. 33(3) PCT).

**Re Item VII.**

- 1 The claims should be renumbered.

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REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/IB2004/000536